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5 COMMON CLINICAL SUPPLY CHAIN SPEEDBUMPS

AND HOW THE RIGHT PARTNER CAN HELP AVOID THEM

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Clinical trials are so complex, you can't leave anything to chance. Instead, you need to connect planning and oversight from sourcing to shipping, and master such requirements as cold chain, border slow-downs and data privacy. Be on the lookout out for these five common issues:

1 The "stuff happens" issue

Preparing for unforeseen events can be especially difficult in pharmaceuticals because of the potential impact on lives. Money isn't the only thing at stake when things go wrong.

Regulations

- The life sciences industry's zero-defect policy applies to everything from the Investigational Medicinal Product to packaging, labeling, delivery and data.
- Standard shippers may not meet all the requirements.

Forecasting

- Connecting production to studies is especially tricky in a fragmented supply chain.
- Beyond investigational material, there are comparators, ancillaries and educational materials.

Planning for the unexpected

- Enrollment changes – up or down – can impact supplies, expiry, shipping and more.
- Interruptions are becoming more common due to weather, pandemics, and geopolitical relationships.

The "stuff happens" solution

Work with companies that adhere to life science levels of quality because lower standards can lead to delays or temperature excursions. A partner with clinical supply planning expertise can also help control the unexpected through forecasting and risk mitigation. But, as with most aspects of drug development, the big payoff comes from deep expertise and visibility up- and down-stream.

2 The "when printing a label isn't just printing a label" issue

Labels are a critical aspect of your trial because you can't correctly dose patients without them. So, this often-overlooked detail can become a major speedbump.

Design

Determine how to fit extended content on the container.

Translation

Generate master English label. Translate into multiple languages. Back-translate. Reconcile translation.

Regulatory

Make sure each country's regulatory requirements are included – in the right place.

Temperature

Develop solutions for any temperature, including sub-zero. Ensure proper adherence so labels won't come off.

The label solution

Work with companies that meet life science levels of quality for clinical labeling – and find a partner who can combine translation, printing and database software to speed up the process. The right partner can reduce label production from months to weeks, or maybe even days.

3 The “slow enrollment and high drop-out issue” issue

Patient recruitment and retention are two of the biggest challenges in clinical trials. A significant percentage of clinical sites fail to enroll a single patient, and about a third of those who do enroll drop out.

Enrollment

- Small, widespread patient populations complicate enrollment.

Participation

- Difficulties getting time off work complicate clinic visits.
- Travel and cost issues multiply if the patient can’t travel alone.

The retention solution

Consider a Direct-to-Patient (DtP) trial format that delivers to patients’ homes, by-passing scheduling and travel issues. Be sure to monitor enrolment and drop-out rates to help adjust supply forecasts, and utilize proactive clinical supply planning to help optimize supplies.

4 The “ensuring patients do it right when nobody is there to watch them” issue

While a DtP design can solve patient needs, it can create problems for you by removing direct oversight of the patient at dosing time, making it harder to track compliance and supply levels.

Dosing

- Packaging that may seem obvious to professionals can be confusing for patients, especially for flexible dosing schemes.
- Incorrect dosing can invalidate patient data and impact the trial.

Tracking

- Storing medicine with patients may result in uncertainty on stock levels and expiry.
- It can also raise questions around cold chain compliance, which may lead to faulty data.

The patient compliance solution

A partner with deep packaging experience can help avoid dosing errors by designing intuitive packages. Add a robust Interactive Response Technology platform to accurately estimate usage, expiry and shipping requirements to avoid stock issues.

5 The “when shipping the drugs seems harder than making them” issue

Even with all the complexities of drug characterization, formulation, solubility and stability, sometimes it feels more difficult to get your therapy to the patient than to make it.

Border issues

- Many countries have different regulations about what can be shipped, and how.
- Regulations frequently change, sometimes while a shipment is in transit.
- Improper paperwork can delay shipments, or even cause them to be turned back.

Shipping mistakes

- Non-clinical shippers may have issues with cold-chain, changing patient needs, or data privacy.
- Damaged shipments can waste huge sums of money — or require a new production run if stocks are low.

The shipping solution

Shipping isn’t just shipping when it’s for a clinical trial. A full-service clinical logistics company will help you avoid delays due to regulations, take advantage of innovations in cold shipping, and benefit from providers who seek the best shipping choices to ensure supplies get to the patients on time.

Thermo Fisher Scientific provides industry leading solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With unwavering commitment to service, science and process engineering, our clinical services team is powered by people with an exceptional commitment to quality and unrivaled expertise. We are exclusively focused on serving the packaging and distribution requirements of clinical trials across the world. Whether planning, packaging, labeling, storing, or distributing the important supplies needed to perform clinical research, we are committed to delivering the highest level of quality, performance, reliability and sustainability through our Patheon Fisher Clinical Services℠ offerings.

The best way to learn more about our clinical trial supply capabilities is to contact us.

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